IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTH DAKOTA

ABBVIE INC. (a Delaware corporation); ALLERGAN, INC. (a Delaware corporation); DURATA THERAPEUTICS, INC. (a Delaware corporation); ABBVIE PRODUCTS LLC (a Georgia limited liability company); PHARMACYCLICS LLC (a Delaware limited liability company); and ALLERGAN SALES, LLC (a Delaware limited liability company),

Plaintiffs,

v.

DREW H. WRIGLEY, in his official capacity as ATTORNEY GENERAL OF THE STATE OF NORTH DAKOTA,

and

TANYA L. SCHMIDT, in her official capacity as BOARD PRESIDENT OF THE NORTH DAKOTA BOARD OF PHARMACY; and CAROLYN BODELL, TYLER G. LANNOYE, SHANE R. WENDEL, KEVIN J. OBERLANDER, DIANE HALVORSON, and RON HORNER, in their official capacities as MEMBERS OF THE NORTH DAKOTA BOARD OF PHARMACY; and MARK J. HARDY, in his official capacity as EXECUTIVE DIRECTOR OF THE NORTH DAKOTA BOARD OF PHARMACY,

Defendants.

Case No. 1:25-cv-00081

HEARING REQUESTED

ABBVIE'S MEMORANDUM IN SUPPORT OF ITS
MOTION FOR SUMMARY JUDGMENT

October 15, 2025

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INTRODUCTION

AbbVie, a biomedical manufacturer that discovers, researches, and produces life-saving medications for all types of diseases and conditions, challenges the constitutionality of a recently enacted North Dakota state law, H.B. 1473. North Dakota's law regulates conduct only under what is called the federal "340B Program." Congress created the 340B Program through Spending Clause legislation as a condition of pharmaceutical manufacturers' participation in federal Medicare Part B and Medicaid. In other words, in exchange for coverage of its products under Medicaid and Medicare Part B, Congress requires AbbVie to agree to participate in the 340B Program. Through the 340B Program, AbbVie offers its drugs for pennies on the dollar (and oftentimes for a single penny per unit) to certain types of nonprofit healthcare providers called "covered entities."

North Dakota's H.B. 1473 is unconstitutional multiple times over. ***First***, and most plainly, H.B. 1473 offends the Constitution's Supremacy Clause. It barges into an exclusively federal field, seeks to change the terms of Congress's own design, and creates a parallel and inevitably conflicting enforcement scheme for purported offenses that Congress placed within the exclusive province of the United States Department of Health and Human Services ("HHS"). ***Second***, North Dakota's new law also constitutes an illicit, uncompensated taking under the Fifth and Fourteenth Amendments by compelling manufacturers to sell their drugs to other private parties at confiscatory prices and on terms to which AbbVie would not otherwise agree in the absence of H.B. 1473. ***Third***, the law offends the Fourteenth Amendment's Due Process Clause by creating impermissibly vague prohibitions that delegate to the State's executive sweeping and unfettered authority to define new crimes ad hoc. ***Fourth***, the law offends the Constitution's Commerce Clause by regulating fully extraterritorial conduct on a discriminatory basis.

The Eighth Circuit's decision in *PhRMA v. McClain*, 95 F.4th 1136 (8th Cir. 2024), is readily distinguishable from the facts presented here. As an initial matter, H.B. 1473 post-dates the *McClain* decision. Further, the *McClain* court did not have occasion to consider a number of issues raised by AbbVie's complaint—including HHS's subsequently finalized ADR Rule and Pilot Rebate Program—and the Arkansas law at issue there was substantively different from North Dakota's law on several fronts. Finally, although *McClain* addressed preemption, it assumed that contract pharmacies remain agents of covered entities and that title does not pass to the pharmacies themselves. *Id.* at 1143. Here, there is no genuine dispute that title ***does*** transfer and that contract pharmacies ***are not*** agents of covered entities. This Court should enter a permanent injunction against H.B. 1473's enforcement.

STATEMENT OF UNCONTESTED FACTS

A. The 340B Pricing Program.

In 1992, Congress enacted Section 340B of the federal Public Health Service Act, establishing what is commonly called the "340B Program." *See* 42 U.S.C. § 256b. Although legislative history and evidence of congressional intent are scant, at least one original goal of the 340B Program was to ensure uninsured and low-income patients receiving care from nonprofit "covered entity" providers could access medications at discounted prices. *See* Ex. 1-A (Air340B Rep.) at 2; Ex. 1-B (HHS Ofc. of Insp. Gen. Memo. Rep.) at 3.

The 340B Program works as follows: In exchange for coverage under federal Medicaid and Medicare Part B, manufacturers must "offer" their drugs to each covered entity "for purchase at or below the applicable ceiling price." 42 U.S.C. § 256b(a)(1). The statute specifically contemplates that manufacturers may offer the "ceiling price" to eligible parties either through a "rebate" or "discount" mechanism. *Id.* The "ceiling price" is set by a statutory formula and results in significant discounts, ranging from 23.1% to more than 99.9% of the average market price for

a given drug—often requiring that manufacturers sell their medicine for as little as one penny per unit. 42 U.S.C. §§ 1396r-8(c), 256b(a)(1). Several of AbbVie's drugs are subject to penny pricing under this scheme. *See* Ex. 3 (Scheidler Decl.) ¶ 31. The average discount across AbbVie's products is approximately ***60%*** of the drugs' commercial value. *Id.* The statutorily enumerated list of "covered entit[ies]" eligible for those prices include, among others, federally qualified health centers such as AIDs clinics and black lung centers, as well as disproportionate share hospitals. 42 U.S.C. §§ 1396r-8(a)(5)(B), 256b(a)(4). The list of covered entities is exclusive and does not include pharmacies or any for-profit entity. *Id.* § 256b(a)(4); *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 60 (D. Del. 2021) ("It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication.").

The federal 340B statute establishes rules that define the rights and obligations of manufacturers, covered entities, and the Secretary of Health and Human Services ("the Secretary"), who administers the 340B Program.

First, the statute prohibits covered entities from selling or "otherwise transferring" drugs they purchased at a 340B discount to anyone who is not a patient of the entity—an act referred to as "diversion." 42 U.S.C. § 256b(a)(5)(B) ("With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not ***resell or otherwise transfer*** the drug to a person who is not a patient of the entity." (emphasis added)). With this restriction, Congress attempted to ensure that the 340B Program did not simply become a buy-low, sell-high scheme for those with a profit motive. *See* Ex. 1-B (HHS Ofc. of Insp. Gen. Mem. Rep.) at 3–4. The statute does not itself define "patient," and therefore the proper definition remains subject to significant dispute. *See* 80 Fed. Reg. 52,300, 52,306–07 (Aug. 28, 2015)

(HRSA guidance purporting to define the term "patient"); *Genesis Health Care, Inc. v. Becerra*, 701 F. Supp. 3d 312, 315 (D.S.C. 2023) (dispute between HHS and covered entities over HRSA's "interpretation of the term 'patient'").

Second, covered entities may not request a Medicaid rebate for a drug purchased at a 340B discount, because doing so would provide a forbidden "duplicate discount[]." 42 U.S.C. § 256b(a)(5)(A)(i). Specifically, the statute provides that "[a] covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act." *Id.* Otherwise, a manufacturer would be required to provide two discounts or rebates on the same product.

Third, covered entities must permit both the Secretary of HHS and manufacturers to audit their records that pertain to the entity's compliance with the prohibitions on diversion and duplicate discounting. *Id.* § 256b(a)(5)(C). Although the statute envisions a limited role for the Secretary in manufacturer-initiated audits, reaching only the power to issue procedures governing "the number, duration, and scope of audits," *id.*, the Secretary has claimed broad substantive, gatekeeping authority over whether audits are warranted in the first instance. *See* 61 Fed. Reg. 65,406 (Dec. 12, 1996). The Health Resources and Services Administration ("HRSA") will not "approve" an audit unless a manufacturer has demonstrated to the satisfaction of the agency that there is "'reasonable cause' to believe that a violation" of the statute's prohibitions on diversion or duplicate discounting "has occurred." *Id.* at 65,408.

Congress vested the Secretary of HHS with broad jurisdiction to enforce the terms of the 340B Program. *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 120–21 (2011). That

includes specific directives from Congress that address manufacturer compliance. 42 U.S.C. § 256b(d)(1)(A)–(B) (instructing the Secretary to, among other things, develop "a system … to verify the accuracy of ceiling prices calculated by manufacturers … and charged to covered entities," establish "procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge," and "develop[] … a mechanism by which … rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered outpatient drugs to covered entities are reported to the Secretary"). That authority also includes specific directives regarding covered entities' compliance. *See id.* § 256b(d)(2)(B)(v) (instructing the Secretary to, among other things, "impos[e] … sanctions" when "a covered entity knowingly and intentionally violates" the prohibitions on diversion and duplicate discounting). As a part of its enforcement authority, HHS may impose civil monetary penalties at a rate of $5,000 for each violation (adjusted for inflation). *Id.* § 256b(d)(1)(B)(vi); 89 Fed. Reg. 64,815, 64,819 (Aug. 8, 2024).

Congress also directed the Secretary to establish an administrative scheme for resolving disputes. HHS must "promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits …, of violations of [the subsections on diversion and duplicate discounting]." 42 U.S.C. § 256b(d)(3)(A). HHS finalized that administrative dispute resolution procedure last year. *See* 89 Fed. Reg. 28,643 (Apr. 19, 2024). To set up the procedure, the Secretary appoints members from the Office of Pharmacy Affairs to serve as an ADR panel that will "[r]eview and evaluate claims, … and documents and information submitted by … covered entities and manufacturers." 42 C.F.R. § 10.20(d)(1). The panel is empowered to "request additional documentation, information,

or clarification" so that it can "[m]ake decisions on each claim." *Id.* § 10.20(d)(2), (d)(5). The panel's findings and conclusions shall remain "binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." 42 U.S.C. § 256b(d)(3)(C).

HHS's regulations concerning the ADR process specify the scope of its jurisdiction. ADR Panels are empowered to hear, among others, "[c]laims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug, ***including claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs*** at or below the 340B ceiling price." 42 C.F.R. § 10.21(a)(1) (emphasis added). When the ADR scheme was under consideration, industry groups representing covered entities specifically advocated for the inclusion of the italicized language. They explained: "We urge HRSA to reinstate language … making clear that covered entities may bring an overcharge claim in situations where a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." Ex. 1-C (340B Health 1/30/2023 Comment Letter) at 1. That is because, in the industry's view, "[w]hen a manufacturer … sets conditions on accessing [the 340B] price, it necessarily means a covered entity must pay more for the drug than the 340B ceiling price." *Id.* The letter continued: "Current manufacturer policies cutting off or conditioning access to 340B pricing for contract pharmac[ies]" are a "type[] of overcharge" and therefore "[i]t is appropriate for an ADR panel to consider these claims." *Id.* at 1–2. Covered entities have since used this procedure to raise disputes with manufacturers over the role of commercial pharmacies in the 340B Program. *See, e.g.*, Ex. 1-D (Open Door Cmty. Health Ctrs. ADR Petition).

The Supreme Court has held that HHS's enforcement authority is exclusive. *Astra*, 563 U.S. at 117. In *Astra*, the Court explained that by vesting enforcement authority solely in HHS, Congress impliedly withheld from covered entities a private right of action to enforce the 340B

Program's requirements against manufacturers. *Id.* "[S]preading the enforcement burden" of the 340B Program "is hardly what Congress contemplated when it 'centralized enforcement in the government.'" *Id.* at 119. Rather, "Congress made HHS administrator of both the Medicaid Drug Rebate Program and the 340B Program" because "the interdependent nature of the two programs' requirements means that an adjudication of rights under one program must proceed with an eye towards any implications for the other." *Id.* at 120. As a result, auxiliary enforcement mechanisms beyond those contemplated in the statute would "undermine the agency's efforts to administer both Medicaid and § 340B ***harmoniously and on a uniform, nationwide basis***." *Id.* (emphasis added).

B. The Rise of "Contract Pharmacies" and Manufacturers' Response.

Initially, commercial pharmacies played a limited role in the 340B Program. It was only after HRSA issued nonbinding guidance that commercial, for-profit pharmacies began to play a substantial and profitable role.

The Rise of Contract Pharmacies. In 1996, HRSA issued guidance opining that covered entities lacking an in-house dispensing pharmacy to receive 340B-priced drugs should be permitted to contract with a *single* outside pharmacy to dispense 340B-priced drugs to their patients.[1] 61 Fed. Reg. 43,549, 43,550–55 (Aug. 23, 1996). Based on the plain text of the 340B statute, contract pharmacies present obvious diversion concerns because they necessarily require the "transfer" of 340B-discounted drugs to "a person who is not a patient of the [covered] entity." 42 U.S.C. § 256b(a)(5)(B). To avoid that issue, HRSA assumed that (i) covered entities would maintain title to the drugs that they purchase and transfer to retail pharmacies and (ii) the pharmacies themselves would remain legal agents of the covered entities. 61 Fed. Reg. at 43,550–

[1] Although the Secretary of HHS lacks rulemaking authority, HRSA, "which administers the program for the Secretary, has issued guidance documents interpreting and implementing the scheme." *Novartis Pharms. Corp.*, 102 F.4th at 456.

55. At that time, HRSA also clarified that this guidance created "no new law" and "no new rights or duties." *Id.* at 43,550. The 340B Program proceeded accordingly for nearly a decade and a half.

The status quo changed in 2010. That year, HRSA released new guidance that purported to permit ***all*** covered entities—even those with their own in-house pharmacy—to contract with an ***unlimited*** number of contract pharmacies, rather than just one pharmacy. 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). Like the 1996 guidance, the 2010 guidance claimed that it did not "impose[] additional burdens upon manufacturers" or "create[] any new rights for covered entities under the law." *Id.*

In the decade following the 2010 guidance, the number of contract pharmacies participating in the program exploded from about 1,300 to 23,000. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 457 (D.C. Cir. 2024). That should surprise no one. Covered entities generate profits from the 340B Program by selling drugs they bought at a discount to patients at full price or by seeking full commercial reimbursement from the patients' insurance plans for these discounted drugs. Covered entities use contract pharmacies to expand this scheme. Ex. 3 (Scheidler Decl.) ¶ 16; Ex. 2 (Williams Decl.) ¶ 19. Contract pharmacies—often multi-billion-dollar, for-profit companies that populate the Fortune 500—receive drugs bought at the 340B discount, sell those drugs at full price, and generate significant profits by sharing with the covered entities the "spread" between the discounted price and price obtained by the pharmacy from the patient and the patient's insurance. So important are 340B profits to these pharmacy chains that, when certain manufacturers stopped making the 340B price available to unlimited pharmacies for each covered entity, CVS and Walgreens identified these policies as a material risk to their business. *See* Ex. 1-E (CVS Pharmacy 10-K (2022)) at 22–23 (explaining that a reduction in contract pharmacy

arrangements "could materially and adversely affect the Company"); Ex. 1-F (Walgreens, Inc. 10-K (2022)) at 33 (similar).

Because contract pharmacies are not a part of the 340B Program (and not among the statutorily enumerated eligible entities), their relationship to covered entities is governed entirely by private contract. Those contracts generally set forth the profit-sharing model between the pharmacy, its third-party administrator (explained in greater detail below), and the covered entity. Ex. 2 (Williams Decl.) ¶¶ 14–19. These contracts are the only way for contract pharmacies to benefit from the "spread" generated when they resell these discounted drugs at full price. *See id.* ¶¶ 14–15. Pharmacies and covered entities generally refuse to share their contracts with manufacturers and consider them confidential and proprietary. *Id.* ¶ 11.

The Replenishment Model. Understanding the basics of the 340B supply chain is important to appreciating the effects of North Dakota's law. At the outset of the 340B Program, contract pharmacies maintained a separate, segregated stock of 340B-priced drugs over which the covered entity maintained title. *See Novartis*, 102 F.4th at 457. The pharmacy dispensed these drugs to the covered entity's patients on its behalf. That is no longer true. *See id.*; Ex. 3 (Scheidler Decl.) ¶ 10. In the vast majority of contract pharmacy arrangements, pharmacies take title to the drugs upon delivery and mix drugs bought at the 340B price with the pharmacy's general inventory, dispensing them to any customer that later walks in the door. Ex. 3 (Scheidler Decl.) ¶¶ 14–15, 18, 20; Ex. 2 (Williams Decl.) ¶¶ 12, 23–24.

This inventory management practice, known as the "replenishment model," is widely used today, including by contract pharmacies in North Dakota. Ex. 2 (Williams Decl.) ¶ 24. Under this model, the contract pharmacy fills all prescriptions using its own drug inventory to all individuals at the point of sale, irrespective of whether they are a covered entity's patient. *Id.* ¶¶ 23–25, 26b.

The pharmacy does not determine at the point of purchase whether the individual receiving the drug is eligible for the 340B discount—nor would that matter to the patient, since patients or their insurers generally pay the full commercial price even for 340B drugs. *Id.* ¶ 26b. Only later, on the back end, does the pharmacy (with the help of a for-profit third-party administrator or TPA) use a black-box algorithm to speculate as to which dispenses ***may*** have been 340B eligible. *Id.* ¶¶ 25, 26c. After the TPA determines that a sufficient number of dispenses for a particular drug were 340B- eligible, an order will be placed for additional quantities of that drug at the 340B price to "replace" the already dispensed medication. *Id.* ¶ 26d. In theory, only the covered entity alone can place this order for drugs at the 340B price. Typically, though, the contract pharmacy or its third-party administrator places the order using the covered entity's account, sometimes without the knowledge of the covered entity. *See* Ex. 3 (Scheidler Decl.) ¶¶ 12, 19. Once the contract pharmacy receives the replenishment order, the 340B-priced drugs become "neutral inventory"—i.e., they are comingled with the pharmacies' general stock—and may be dispensed to any subsequent patient—340B or not. Ex. 2 (Williams Decl.) ¶¶ 23–24.

This arrangement has led to a significant uptick in unlawful transactions. The HHS Office of Inspector General (OIG) has found that contract pharmacy arrangements create a greater risk of diversion, i.e., that discounted drugs are dispensed to customers who are not covered entity patients. Ex. 1-B (HHS Office of Inspector General Report (Contract Pharmacy Arrangements in the 340B Program)) at 1–2. That is because, in reality, the contract pharmacies' 340B criteria used for the algorithm are often materially overinclusive, sweeping in individuals that are no longer receiving prescriptions as a patient of a covered entity. *See* Ex. 2 (Williams Decl.) ¶¶ 32–38; Ex. 3 (Scheidler Decl.) ¶¶ 12–13. This enables the covered entity and its pharmacies to maximize their arbitrage profits. Indeed, "[t]he covered entity, the pharmacy, and the third-party administrator

often divvy up the spread between the discounted price and the higher insurance reimbursement rate" and thus each actor "has a financial incentive to catalog as many prescriptions as possible as eligible for the discount." *Novartis*, 102 F.4th at 457–58. Importantly, contract pharmacies usually take title to the 340B drugs and do not maintain an agency relationship with the covered entities. *See* Ex. 3 (Scheidler Decl.) ¶¶ 14–15, 18, 20; Ex. 2 (Williams Decl.) ¶ 13.

The contract pharmacy explosion has not directed more care to the needy or lowered costs for patients. Among the 340B hospitals surveyed by the U.S. Government Accountability Office, approximately half of covered entities admit that they do not pass on ***any*** discounts to patients at contract pharmacies—others admit they do so only rarely. Ex. 1-G (GAO Rep., GAO-18-480) at 35, 43–44; *see also* Ex. 1-H (IQVIA White Paper) at 3 ("[M]ost 340B-eligible patients at contract pharmacies are not directly benefiting from 340B discounts."). Industry experts have observed that needy patients scarcely benefit from expansions in the 340B Program, and many patients continue to see no real benefit at all. Ex. 1-H (IQVIA White Paper) at 12; Ex. 1-I (Fein WSJ Article) at 2; Ex. 1-J (Lin JK Letter for JAMA) at 2 (observing that, during the contract-pharmacy explosion, the share of 340B retail pharmacies in socioeconomically disadvantaged neighborhoods declined even though the share of all retail pharmacies in those neighborhoods increased); Ex. 1-K (Fein Letter) at 7–8. Some even suggest that charity care to the needy ***declined*** during the commercial pharmacy explosion, with a majority of 340B hospitals providing even less charity care, on average, than ordinary hospitals. Ex. 1-A (Air340B Rep.) at 2–3; Ex. 1-L (Fein Charity Care Article) at 3–4.

Manufacturers' Policies. Starting in 2020, several drug manufacturers adjusted their 340B policies in response to startling contract-pharmacy abuse. In 2023, AbbVie announced its 340B Program Integrity Initiative. Ex. 3 (Scheidler Decl.) ¶ 4. That policy (most recently updated

in July 2025) allows hospital covered entities to direct transfer AbbVie's 340B-priced drugs to their in-house pharmacies. *See id.* ¶¶ 4–6. If a covered entity lacks an in-house pharmacy, it may direct transfer AbbVie's 340B-priced drugs to a single contract pharmacy of its choice within 40 miles, provided that it also supplies limited "claims data." *Id.* ¶ 5. AbbVie is committed to ensuring each hospital covered entity has at least one pharmacy location to receive and dispense discounted drugs and, if necessary, will work with covered entities to identify alternatives to the 40-mile requirement. *Id.* ¶¶ 4–5. Plus, federal grantees may place orders for direct delivery to an unlimited number of contract pharmacies as long as the grantee registers with a free web-based platform and submits claims data. *Id.* ¶ 5. AbbVie continues to offer unlimited 340B-priced drugs to all covered entities, as the 340B statute requires. Accordingly, AbbVie's policy in no way affects patient access to 340B-discounted drugs. *Id.* ¶ 4.

C. Federal Courts Approve Manufacturers' Contract-Pharmacy Limitations.

In response to manufacturers' adopting policies limiting the use of contract pharmacies, HHS issued an Advisory Opinion in December 2020 declaring that Section 340B requires manufacturers to transfer discounted drugs to an unlimited number of contract pharmacies. Ex. 1-M (HHS Advisory Opinion 20-06) at 3. A few months later, the government sent AbbVie and other manufacturers violation letters purporting to enforce the 340B statute, stating that AbbVie's policy (and others) resulted in "overcharges." *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 701 (3d Cir. 2023). The 2020 Advisory Opinion was ultimately withdrawn after a federal district court determined that it was unlawful. *See AstraZeneca Pharms. LP*, 543 F. Supp. 3d at 47.

Litigation continued, and manufacturers prevailed. The Third Circuit endorsed manufacturer policies that limit the indiscriminate transfer of discounted drugs to commercial pharmacies, emphasizing that Congress intentionally "chose not to" impose contract-pharmacy

obligations on manufacturers. *Sanofi*, 58 F.4th at 703–07; *see id.* at 704 ("[Congress] had in mind one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies."). The D.C. Circuit agreed. It held that the 340B Program "merely requires manufacturers to propose to sell covered drugs to covered entities at or below a specified monetary amount." *Novartis*, 102 F.4th at 460. It does not "subject manufacturers to whatever delivery conditions any covered entity might find most convenient." *Id.* at 461. Rather, the 340B statute "preserve[d]" manufacturers' ability to include reasonable conditions on their offers. *See id.* at 460, 463–64.

D. HRSA Announces the Pilot Rebate Program.

On top of the long-running disputes within the 340B Program, other issues have evolved arising from a new federal drug-pricing program: the so-called "Drug Price Negotiation Program" ("DPNP") created by the Inflation Reduction Act of 2022. *See* 42 U.S.C. § 1320f; Ex. 1-N (CMS Selected Drugs) at 2 (selecting one drug that AbbVie manufactures, Imbruvica). The DPNP requires the Secretary of HHS to set "maximum fair prices" ("MFPs") for drugs selected under the program. *See* 42 U.S.C. § 1320f(a)(3). Manufacturers of selected drugs must ensure the MFP is applied to drugs dispensed by hospitals and pharmacies that provide care to Medicare-covered individuals. *Id.* §§ 1320f(c)(2), 1320f-2(a)(3). If a manufacturer fails to do so, it can face civil monetary penalties reaching millions of dollars per day. 42 U.S.C. §§ 1320f-6(c), 1320f-2(a)(5).

Patients often receive prescriptions for drugs selected under the DPNP from 340B-covered entities. When that happens, there are two potentially applicable prices for the same drug dispense: the 340B ceiling price and the MFP. To address that issue, the DPNP contains a non-duplication provision, which obligates manufacturers to provide only the lower of the MFP and the 340B discount price. *Id.* § 1320f-2(d). It is the manufacturer's responsibility to determine the appropriate price for any given dispense. *See* Ex. 1-O (2027 Guidance) at 231 ("CMS will not, at

this time, assume responsibility for nonduplication of discounts between the 340B ceiling price and MFP."); *id.* at 54 ("Neither CMS nor the [system facilitating data flow between CMS, manufacturers, and providers] will verify that a claim was or was not billed as a 340B-eligible drug.").

Widespread concern among manufacturers regarding their ability to avoid duplicate discounting prompted HRSA to announce a pilot program in which manufacturers will use a rebate model—i.e., provide a post-dispense discount to the covered entity rather than making the initial sale to the covered entity at the 340B price. 90 Fed. Reg. 36,163 (Aug. 1, 2025). HRSA's program specifically contemplates that manufacturers will condition 340B rebates upon covered entities submitting claims data for dispenses. *Id.* at 36,164–65. This is because claims data is the most accurate and efficient method for ensuring compliance with the DPNP's non-duplication provision. *See* Ex. 3 (Scheidler Decl.) ¶ 25; Ex. 2 (Williams Decl.) ¶¶ 20, 26c, 29. It allows manufacturers to quickly identify which dispenses were both MFP- and 340B-eligible.

AbbVie currently has one drug that is subject to both the ceiling price and the maximum fair price. Ex. 3 (Scheidler Decl.) ¶ 26. AbbVie is therefore eligible to participate in the Rebate Program and has submitted its application. *See id.* ¶ 27. Based on AbbVie's conversations with HRSA and HRSA's vision for the program, it appears that AbbVie will participate in the Rebate Program. *Id.* AbbVie also expects that more of its drugs may be selected in the future for inclusion in the DPNP. *See id.* ¶ 26; Ex. 1-N (CMS Selected Drugs) at 2.

E. North Dakota Attempts to Undo the Federal Rulings.

In the aftermath of the federal courts of appeals confirming the lawfulness of contract-pharmacy policies, states started enacting their own 340B contract-pharmacy laws. This case concerns North Dakota's decision to join that effort by enacting H.B. 1473. The statute applies only to putative transactions under the federal 340B Program. And it defines its terms by reference

to the federal program itself: a "drug" is "a drug purchased under reduced pricing under section 340B of the federal Public Health Service Act [42 U.S.C. 201 et seq.] by a covered entity." N.D. Cent. Code § 43-15.3-08(3)(a)(3). And a "contract pharmacy" is "a pharmacy that has a contract with a covered entity to receive and dispense drugs to the covered entity's patients on its behalf." *Id.* § 43-15.3-08(3)(a)(1). From there, H.B. 1473 imposes a series of ***additional*** obligations on pharmaceutical manufacturers that participate in the federal program.

First, the statue provides "[A] manufacturer, an agent or affiliate of that manufacturer, virtual manufacturer, or third-party logistics provider of a manufacturer's drugs" may not "[d]irectly or indirectly deny, restrict, prohibit, or otherwise interfere with the acquisition of a drug by a contract pharmacy on behalf of a covered entity unless receipt of the drug is prohibited by federal law." *Id.* § 43-15.3-08(3)(b)(1).

Second, manufacturers may not "[p]rohibit a contract pharmacy from dispensing a drug by denying access to the drug." *Id.* § 43-15.3-08(3)(b)(2). These provisions appear to broadly prohibit manufacturers from imposing contract-pharmacy conditions in their 340B offers—the type of conditions that the Third and D.C. Circuits said the federal statute preserves the right of manufacturers to include.

Third, H.B. 1473 says that a manufacturer may not "[r]equire a covered entity or contract pharmacy to submit any claims, encounter, or utilization data as a condition for acquiring or receiving a drug, unless the claims, encounter, or utilization data sharing is required by federal law." *Id.* § 43-15.3-08(3)(b)(3). Claims data is ubiquitous throughout the healthcare industry. Ex. 3 (Scheidler Decl.) ¶ 23. Pharmacies, hospitals, and other organizations already generate this data in the ordinary course of their business to seek insurance reimbursement, among other purposes. *See id.* It is therefore minimally burdensome to provide. *See Novartis*, 102 F.4th at

463. The only effect of this provision is to shield abuse of the 340B Program from manufacturers and prevent them from using data in the 340B Program's remedial scheme.

Fourth, manufacturers may not "[i]nterfere with the ability of a covered entity or contract pharmacy to dispense a drug to an eligible patient of the covered entity." N.D. Cent. Code § 43-15.3-08(3)(b)(4). This broad catchall provision has no clear effect that is not already covered under subsections (3)(b)(1)–(3).

Fifth, a manufacturer may not "[o]ffer or otherwise make available a drug in the form of a rebate, unless in the form of a discount at the time of sale and authorized under federal law." *Id.* § 43-15.3-08(3)(b)(5). This provision thrusts North Dakota into the center of ongoing litigation between HHS and manufacturers participating in the 340B Program over the scope of the agency's ability to limit manufacturers from providing access to 340B pricing through a rebate rather than an upfront discount. *See Novartis Pharms. Corp. v. Kennedy*, No. 25-5177 (D.C. Cir. appeal docketed May 21, 2025).

Violations of these provisions are class B misdemeanors. N.D. Cent. Code § 43-15.3-08(3)(b). Such violations are enforceable by the Attorney General under his general enforcement authority. *Id.* §§ 54-12-01(2), 54-12-02; *see also* Answer to Am. Compl. ¶ 107. Another entity, the State Board of Pharmacy, may seek civil penalties and injunctive relief. *See* N.D. Cent. Code § 43-15.3-09(1)–(2).

AbbVie filed this lawsuit shortly after H.B. 1473's enactment, seeking declaratory and permanent injunctive relief. Am. Compl. ¶¶ 124–31.

LEGAL STANDARD

This Court should grant summary judgment if there is no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a).

ARGUMENT

H.B. 1473 cannot be squared with the Federal Constitution. ***First***, the 340B Program preempts H.B. 1473 in several respects—the most glaring conflict being the State's overlapping enforcement scheme. ***Second***, H.B. 1473 effects a taking in violation of the Fifth and Fourteenth Amendments by compelling a private-to-private, physical transfer or, in the alternative, through a regulatory taking. ***Third***, H.B. 1473 is impermissibly vague under the Fourteenth Amendment's Due Process Clause. ***Fourth***, North Dakota's law regulates out-of-state transactions on a discriminatory basis in violation of the Commerce Clause.

I. NORTH DAKOTA'S LAW IS PREEMPTED.

Under the Constitution's Supremacy Clause, federal law "shall be the supreme Law of the Land; … any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Although both the National and State governments enjoy certain spheres of authority, there are circumstances in which State law must "give way to federal law." *Arizona v. United States*, 567 U.S. 387, 399 (2012). Courts generally recognize two separate but related implied preemption doctrines: conflict and field preemption. *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). North Dakota's H.B. 1473 runs afoul of both doctrines, but AbbVie focuses on conflict preemption.[2]

[2] H.B. 1473 is also preempted because it unconstitutionally intrudes on the field of 340B drug pricing, which Congress fully occupied with a single comprehensive federal scheme with a curated set of obligations, eligibility criteria, and enforcement mechanisms. Congress's system, which preserves manufacturers' right to condition their offers, *see Novartis*, 102 F.4th at 460, is "so pervasive" that there is "no room for the States to supplement it," *Arizona*, 567 U.S. at 399 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

A. H.B. 1473 Is Conflict Preempted.

The Supreme Court has made clear that "state laws are preempted when they conflict with federal law," which includes "those instances where the challenged state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Arizona*, 567 U.S. at 399 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). What constitutes "a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." *Crosby*, 530 U.S. at 373.

Here, H.B. 1473 conflicts with the federal 340B Program in four concrete ways. ***First***, H.B. 1473 sets up a conflicting enforcement scheme with the federal program. ***Second***, H.B. 1473 obstructs the 340B audit process. ***Third,*** H.B. 1473 interferes with manufacturers' participation in the federal Rebate Program. ***Fourth***, H.B. 1473 restricts rights conferred under the federal 340B Program, interrupting the uniformity and balance Congress struck in the 340B Program.

1. *H.B. 1473 sets up a conflicting enforcement scheme.*

H.B. 1473 interferes with Congress's desire for a unified 340B enforcement scheme by creating a parallel state regime. That is a problem for H.B. 1473 because the Supreme Court has been clear that the Supremacy Clause nullifies "conflict[ing] … method[s] of enforcement" on the ground that "a conflict in technique can be fully as disruptive to the system Congress erected as conflict in overt policy." *Arizona*, 567 U.S. at 406–07 (quoting *Motor Coach Emps. v. Lockridge*, 403 U.S. 274, 287 (1971)); *see also Crosby*, 530 U.S. at 373 (concluding a state law was "an obstacle to the accomplishment of Congress's full objectives"). That is the situation North Dakota's new 340B law finds itself in.

In *Astra*, the Supreme Court concluded that Congress vested HHS with exclusive authority to "oversee compliance with the 340B Program." *Astra*, 563 U.S. at 117. Congress instructed the Secretary to exercise broad powers over both manufacturer and covered-entity compliance with

340B. 42 U.S.C. § 256b(d)(1)–(2). Key to the Secretary's authority is Congress's delegation of authority to "promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits …, of violations of [the subsections on diversion and duplicate discounting]." *Id.* § 256b(d)(3)(A).

HHS exercised that grant of authority when it created an exclusive federal forum for disputes between manufacturers and covered entities over alleged overcharging, duplicate discounts, and diversion. *See* 89 Fed. Reg. 28,643 (Apr. 19, 2024). These ADR panels hear claims that a manufacturer has "limited" a covered entity's ability to purchase 340B-priced drugs. *See Astra*, 563 U.S. at 117. Their decisions bind the parties "unless invalidated by an order of a ***Federal*** court," and they have jurisdiction over "[c]laims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug, ***including claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price***." 42 C.F.R. § 10.21(a)(1), (c) (emphasis added).

HHS and covered entities agree such claims include disputes about the limiting covered entities' "acquisition" of 340B drugs, including by limiting the use of contract pharmacies. For example, one large covered-entity group "urge[d] HRSA to … mak[e] clear that covered entities may bring an overcharge claim in situations where a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." Ex. 1-C (340B Health 1/30/2023 Comment Letter) at 1. This includes, in the view of covered entities, "manufacturer policies cutting off or conditioning access to 340B pricing for contract pharmac[ies]" are a "type[] of overcharge[]" and therefore "[i]t is appropriate for an ADR panel to consider these claims." *Id.* at 2. HHS agreed and "modified § 10.21(a)(1) to further explain

that an overcharge claim generally includes claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." *See* 89 Fed. Reg. at 28,649.

H.B. 1473 establishes a separate remedial scheme that conflicts with the federal ADR process. Like the federal system, North Dakota's law covers disputes between manufacturers and covered entities over the use of contract pharmacies. It goes further, though, resolving all those disputes the same way. Under North Dakota's law, manufacturers may not limit the number of pharmacies with which a covered entity may contract or require claims data. *See supra* pp. 17–19. The statute then appoints North Dakota's Attorney General and its Board of Pharmacy to seek civil penalties and injunctive relief in North Dakota state courts to enforce H.B. 1473's violations. N.D. Cent. Code §§ 43-15.3-09(1)–(2), 54-12-01(2), 54-12-02.

In other words, North Dakota purports to adjudicate the same complaints as the exclusive federal ADR forum. *Compare* 42 C.F.R. § 10.21(a)(1), *with* N.D. Cent. Code § 43-15.3-08(3)(b)(1), (b)(3). H.B. 1473 attempts to replace the federal ADR panels with its state courts and Board of Pharmacy. N.D. Cent. Code §§ 43-15.3-09(1)–(2), 54-12-01(2), 54-12-02. The law does so in the face of HHS's exclusive and unified power to "administer … § 340B harmoniously and on a uniform, nationwide basis." *Astra*, 563 U.S. at 120.

Making matters worse, the competing federal and state systems may involve competing interpretations of federal law. Indeed, North Dakota officials must interpret and apply 340B itself when they execute H.B. 1473. For example, AbbVie might defend itself in a H.B. 1473 proceeding by arguing that the entity who ordered drugs was engaging in unlawful diversion or was otherwise ineligible for 340B discounts. *See* N.D. Cent. Code § 43-15.3-08(3)(a)(2) (applying to "an entity participating or authorized to participate in a federal drug discount program under 42 U.S.C.

§ 256b"). But those issues are reserved for the federal 340B dispute-resolution system, which Congress created specifically to adjudicate claims arising within the 340B Program, to provide remedies to injured parties, and to impose sanctions on offenders. *See* 42 U.S.C. § 256b(d)(1)–(3); *see also* 42 C.F.R. § 10.21(a).

The Southern District of West Virginia reached the same result in *PhRMA v. Morrisey*, 760 F. Supp. 3d 439 (S.D. W. Va. 2024), concluding that such overlapping enforcement regimes obstruct Congress's aims. The result is a hodgepodge of state and federal adjudicators deciding the same purely federal questions in potentially inconsistent ways. That "risk of conflicting results cuts against Congress's vision of 'centralized enforcement' that *Astra* found as necessary to execute the 340B Program." *Id.* at 458.

Indeed, if North Dakota's scheme is upheld, HHS's exclusive, nationwide authority is obliterated in favor of dozens of state attorneys general, boards of pharmacy, and courts—each with their own view of what makes good 340B policy. *Contra Astra*, 563 U.S. at 119–20 (explaining that "spreading the enforcement burden" and permitting "suits by 340B entities would undermine the agency's efforts to administer" the 340B Program). North Dakota's plan would "spawn a multitude of dispersed and uncoordinated lawsuits" both by "340B entities" and State enforcers. *Id.* at 120. "With HHS unable to hold the control rein, the risk of conflicting adjudications would be substantial." *Id.* North Dakota's law is an unabashed attempt to undo *Astra*, but North Dakota cannot do that.

This newfangled and divided enforcement plan offends the elementary preemption principle that "conflict in technique can be fully as disruptive to the system Congress erected as conflict in overt policy." *Wis. Dep't of Indus., Lab. & Hum. Rels. v. Gould Inc.*, 475 U.S. 282, 286 (1986) (quoting *Motor Coach*, 403 U.S. at 287). No state may regulate what the 340B Program

either "protects" or potentially "prohibits" because "conflict is imminent whenever two separate remedies are brough to bear on the same activity." *Id.* (citation modified); *see also Crosby*, 530 U.S. at 380 ("[T]he inconsistency of sanctions here undermines the congressional calibration of force.").

It is well established that overlapping enforcement mechanisms create a conflict, even if the schemes may share the same goal. For example, in *Arizona*, the state adopted immigration laws with, in its view, "the same aim" and "substantive standards" as federal law. *See* 567 U.S. at 402. One provision made it a misdemeanor to willfully fail to "complete or carry an alien registration document" in violation of federal law. *Id.* at 400. This provision added a "state-law penalty for conduct" that was already "proscribed by federal law." *Id.* It was nonetheless preempted because "federal statutory directives provide a full set of standards governing alien registration, including punishments for noncompliance." *See id.* at 401. Congress's directives were designed as a "harmonious whole," so they displaced "even complementary state regulation." *Id.*

2. *H.B. 1473 conflicts with the 340B audit process.*

North Dakota's law also conflicts with the federal 340B dispute-resolution scheme because it restricts manufacturers' access to claims data. Under H.B. 1473, manufacturers cannot condition the acquisition or receipt of a 340B-priced drug on the submission of "any claims, encounter, or utilization data." N.D. Cent. Code § 43-15.3-08(3)(b)(3).

Manufacturers use claims data to identify audit targets and otherwise police abuse of the 340B Program. Ex. 3 (Scheidler Decl.) ¶ 25. For example, claims data for a dispensing event may reveal whether a covered entity has submitted duplicate claims for DPNP and 340B discounts. *Id.* Claims data may also clarify whether a covered entity's replenishment order double (or triple, or quadruple) counts a single patient's prescription. *Id.*

H.B. 1473's claims data prohibition creates a direct obstacle to the federal 340B audit process. Audits allow manufacturers to access the federal ADR process and enforce the 340B Program's requirements. *See* 42 U.S.C. § 256b(d)(3)(A). To access the audit process, a manufacturer needs "reasonable cause." A manufacturer cannot establish "reasonable cause" without documentation sufficient for a reasonable person to believe that the "covered entity may have violated" the prohibitions on diversion or duplication. 61 Fed. Reg. at 65,407, 65,409. Unsurprisingly, then, HHS has recognized that a manufacturer conducting an audit must be able to review "the covered entity's records of drug procurement and distribution," among other things. *Id.* at 65,410. Claims data unlocks the ADR process. Without it, there is no audit—and without an audit, there is no ADR option.

Morrisey recognized this problem too, concluding that West Virginia's claims-data prohibition "hamper[ed] the ability of drug manufacturers to formulate the 'reasonable cause' necessary to conduct an audit" and that "[w]ithout an audit, Plaintiffs [had] no ability to access the federally administered alternative dispute resolution system set up by the 340B Program." 760 F. Supp. 3d at 453. Because West Virginia's prohibition went "well beyond simple tension with the federal objectives," the court preliminarily enjoined it. *Id.* at 453, 464.

Here, as in *Morrisey*, "a state law must not create an obstacle" to the twin federal purposes of "providing discounts to covered entities only *and* prohibiting fraud through duplicate discounts." *Id.* at 452. But H.B. 1473's claims-data prohibition does just that. *See Crosby*, 530 U.S. at 372–73. It guts the 340B Program's anti-fraud provisions by "establish[ing] a system where the fox guards the hen house"—that is, a system where a covered entity or contract pharmacy need only provide claims data when, or if, it sees fit. *Morrisey*, 760 F. Supp. 3d at 453.

Section 340B did not contemplate such an unstable arrangement. In fact, its anti-fraud provisions and audit system seek the exact opposite result.

3. *H.B. 1473 obstructs participation in a federal program.*

H.B. 1473 also substantially interferes with AbbVie's ability to participate in the federal Rebate Model Pilot Program. A state law is preempted if it conflicts with federal law, or if it "interferes with the methods by which the federal statute was designed to reach th[at] goal." *Forest Park II v. Hadley*, 336 F.3d 724, 733 (8th Cir. 2003). HRSA—the federal agency responsible for implementing the 340B statute—created the Rebate Program to address concerns related to both the 340B Program and the Inflation Reduction Act. *See* Ex. 3 (Scheidler Decl.) ¶ 25. North Dakota attempts to hurl itself in front of the federal government's chosen path, but the Constitution does not permit it to do so. *See Forest Park II*, 336 F.3d at 733.

First, North Dakota's H.B. 1473 purports to prohibit rebate mechanisms outright. N.D. Cent. Code § 43-15.3-08(3)(b)(5) (stating that manufacturers may not "[o]ffer or otherwise make available a drug in the form of a rebate, unless in the form of a discount at the time of sale and authorized under federal law"). But the 340B Program permits rebate mechanisms—and now that HRSA has created the Rebate Program, manufacturers are expressly encouraged to adopt them. This fact is so plain that parties to ongoing litigation over the Rebate Program disagree only about the *extent* of HRSA's supervisory authority over rebate mechanisms. *See Novartis Pharms. Corp. v. Kennedy*, No. 25-5177 (D.C. Cir. appeal docketed May 21, 2025). By forbidding rebate mechanisms, H.B. 1473 attempts to override HRSA's judgment.

Second, North Dakota's claims-data restriction substantially interferes with AbbVie's ability to participate in the Rebate Program. The Rebate Program expressly contemplates that participating manufacturers will condition rebates on covered entities and contract pharmacies providing claims data. *See* 90 Fed. Reg. at 36,164–65. Yet North Dakota's law prevents AbbVie

from requiring covered entities to provide those data as a participant in the Rebate Program. N.D. Cent. Code § 43-15.3-08(3)(b)(3). By enforcing its law, North Dakota obstructs AbbVie's participation in a federal program—something no state has the power to do. *See Forest Park II*, 336 F.3d at 732 ("Simply, state statutes may not interfere with the implementation of a federal program by a federal agency.").

4. *H.B. 1473 restricts rights conferred under the federal 340B Program.*

North Dakota's law again frustrates Congress's judgment by restricting rights Congress conferred on manufacturers. A state law is obstacle preempted when a federal program confers a right on private actors that conflicts with the state law's restrictions. *See Murphy v. Nat'l Collegiate Athletic Ass'n*, 584 U.S. 453, 477 (2018). The 340B Program confers at least one such right by reserving to manufacturers a right to place reasonable conditions on their 340B offers. *See Novartis*, 102 F.4th at 460; *Sanofi*, 58 F.4th at 703. Among those conditions are limits on the number of pharmacies with which a covered entity may contract and "minimal[ly]" "burden[some]" requests for claims data. *Novartis*, 102 F.4th at 463. Indeed, HRSA assumes that manufacturers have the power to request claims data. *See* 90 Fed. Reg. at 36,165. Yet H.B. 1473 eliminates manufacturers' ability to attach reasonable conditions.

Instead, it requires manufacturers to make offers using ***the State's*** terms. The federal 340B statute requires only that manufacturers make a reasonable ***offer*** at the discounted price. *Novartis*, 102 F.4th at 460. Under the statute, manufacturers need only make such offers to covered entities, since "[n]owhere does Section 340B mention contract pharmacies … [n]or does the word 'offer' imply that the offeror must deliver goods wherever and to whomever the buyer demands." *Sanofi*, 58 F.4th at 703. This statutory "silence" actually "preserves—rather than abrogates—the ability of sellers to impose at least some delivery conditions." *Novartis*, 102 F.4th at 460. It does so because of "background contract principles" that operate on the part of Section 340B "requir[ing]

manufacturers to ***offer*** each covered entity covered outpatient drugs for purchase." *Id.* (emphasis added). Ordinarily, offers "may contain both price and non-price terms"—in the 340B context, that means conditions limiting the provision of discounted drugs to contract pharmacies and conditions requiring basic data submissions. *Id.*

That is where H.B. 1473 intervenes, insisting that ***any*** conditions are off limits, N.D. Cent. Code § 43-15.3-08(3)(b)(3), and thereby requiring manufacturers to complete significantly more sales at the discounted price. This attempt to revise the federal scheme is destabilizing. Congress designed the 340B Program around voluntary manufacturer participation. *See Novartis*, 102 F.4th at 460. When Congress used its Spending Clause authority to attach the 340B Program's obligations to Medicaid and Medicare, imposing one more condition on manufacturers in exchange for those programs' substantial benefits, it made a reasoned judgment on which conditions were proper to participate in 340B. That judgment preempts contrary state enactments, *see Mo. Child Care Ass'n v. Cross*, 294 F.3d 1034, 1041 (8th Cir. 2002) ("[U]nder the Supremacy Clause, federal Spending Clause legislation trumps conflicting state statutes or regulations.")—including where states append their own conditions, changing the terms of its deal to accomplish various local priorities. H.B. 1473 is preempted to the extent it pursues that unconstitutional end.

In that way, H.B. 1473 "interfere[s] with the careful balance struck by Congress." *Arizona*, 567 U.S. at 406. Congress wanted to make some drugs available at below-market prices. And it wanted drug manufacturers to provide those drugs, at that price, of their own volition. So Congress made the 340B Program narrow enough—for example, by requiring discounted sales only to the enumerated covered entities—to prevent manufacturers from withdrawing altogether. That limited scope is "no less a part" of Congress's "purpose" than its other substantive goal—drug discounts. *Rapanos v. United States*, 547 U.S. 715, 752 (2006). The 340B Program thus has the "twin federal

purposes" of providing discounts to covered entities and protecting manufacturers. *Morrisey*, 760 F. Supp. 3d at 452. North Dakota obstructs Congress's aims by skewing that balance and emphasizing one of 340B's ends to the exclusion of the other. Congress's effort to protect manufacturers is no mere subcomponent of its effort to make drugs accessible to underserved populations. As courts have long recognized, "no law pursues its purpose at all costs." *Rapanos*, 547 U.S. at 752. Section 340B depends on voluntary participation. As such, participating manufacturers' rights are equally as important to the Program as their obligations. Among those rights are reasonable offer terms like contract-pharmacy limitations and claims-data requirements. H.B. 1473 manipulates that balance by eliminating manufacturers' rights.

B. *McClain* Does Not Control and Does Not Save H.B. 1473.

PhRMA v. McClain, 95 F.4th 1136 (8th Cir. 2024), does not control AbbVie's preemption claim. In *McClain*, an association of pharmaceutical manufacturers sued in Arkansas to enjoin enforcement of that state's H.B. 1473 analog and argued that it was preempted by the 340B Program and the Federal Food, Drug, and Cosmetic Act. *Id.* at 1139. Based on the specific arguments made and the limited record before the District Court, the Eighth Circuit held that those federal statutes did not preempt Arkansas's law. *Id.* at 1145–46.

McClain is distinguishable for several reasons. For example, PhRMA did not plead claims based on an unconstitutional taking or the dormant commerce clause, as AbbVie does here. But with respect to preemption in particular, ***first***, the statutory language at issue in *McClain* was materially different from H.B. 1473. There, Arkansas's statute prohibited manufacturers from "denying access" to "340B drug pricing" for pharmacies who had contracts with participating 340B-covered entities. Ark. Code Ann. § 23-92-604(c). *McClain* concluded that prohibiting manufacturers from "denying access" to the 340B price was a "delivery" regulation within the state's police power that was not preempted because the federal statute is "silent about delivery of

drugs." 95 F.4th at 1142. Even assuming *McClain* was correct that Arkansas's law regulates delivery (which AbbVie does not concede), H.B. 1473 was enacted after that decision and, importantly, it ***does not mention "delivery"*** but regulates only "acquisition." N.D. Cent. Code § 43-15.3-08(3)(b)(1); *Sanders v. Union Pac. R&R Co.*, 108 F.4th 1055, 1061 (8th Cir. 2024) (departing from past circuit precedent when underlying statute had been amended in the interim). The Eighth Circuit did not examine a statute that compels AbbVie to permit the "acquisition" of its private property at confiscatory prices in *McClain* or otherwise (not in the least because *McClain* did not evaluate a takings claim).

Second, *McClain* relied on a limited factual record and assumptions that do not hold here. The Eighth Circuit assumed that the Arkansas law conformed with HRSA's initial understanding of how covered-entity/contract-pharmacy relationships would function—that contract pharmacies remain agents of covered entities and that title does not pass to the pharmacies themselves. *McClain*, 95 F.4th at 1144; *see* 61 Fed. Reg. 43,549, 43,550–55. It also assumed that contract pharmacies do not purchase the drugs themselves. *McClain*, 95 F.4th at 1144. Based on those assumptions, the court rejected the manufacturers' argument that Arkansas's law "impermissibly interfere[d] with 340B's 'closed system' by adding pharmacies to the enumerated list of covered entities eligible to receive 340B pricing on drugs." *Id.* at 1144 (concluding PhRMA "misconstrue[d]" the Arkansas statute because, in Arkansas, "[p]harmacies do not purchase 340B drugs" or "receive the 340B price discounts" and "[c]overed entities purchase and maintain title to the 340B-discounted drugs").

Here, there is no genuine dispute that title ***does*** transfer and that contract pharmacies ***are not*** agents of covered entities. Ex. 3 (Scheidler Decl.) ¶¶ 15, 18, 20; Ex. 2 (Williams Decl.) ¶ 13. And even though covered entities may often place orders *through* a covered entity's account, it is

their third-party administrators placing orders to replenish the pharmacies' stock. *See* Ex. 3 (Scheidler Decl.) ¶¶ 12, 19; Ex. 2 (Williams Decl.) ¶ 26d. *McClain*'s assumptions do not hold in this case, where contract pharmacies place orders for drugs, receive those drugs, and then retain title to them. *McClain*'s conclusion that laws like H.B. 1473 do not functionally add contract pharmacies to the list of entities eligible to purchase drugs at 340B prices, *see* 95 F.4th at 1145, was based on factual conclusions not present here. *McClain*'s conclusion is inapposite.

Another district court in the Eighth Circuit recently recognized the limits of *McClain*. In *AstraZeneca Pharmaceuticals LP v. Harris*, 4:24-cv-00268 (E.D. Ark. Sept. 30, 2025), the manufacturer argued that Arkansas's H.B. 1473 analog was preempted because it regulated drug ***price*** in violation of federal patent law and alleged what AbbVie has evidenced here—title of the drug transfers to contract pharmacies and contract pharmacies are not agents of covered entities. Order, *Harris*, No. 4:24-cv-00268, ECF No. 142 ("*Harris* Order"), at 12. The court recognized that, on these points, *McClain* is inapposite and concluded that the manufacturer plausibly pleaded its preemption claim. *Id.* The manufacturer there also plausibly alleged that Arkansas's law impermissibly obstructed the manufacturer/federal government relationship, by substantially impairing the terms of AstraZeneca's pharmaceutical pricing agreement and "expand[ing] [AstraZeneca's] obligations" under the 340B Program. *Id.* at 13. *Harris* demonstrates that *McClain* must be read in light of the facts and arguments it confronted, both of which are different here.

Nor does *McClain* control or guide the court's analysis of any of AbbVie's other claims. *McClain* did not address a law with claims data and rebate prohibitions that directly conflict with HRSA's ADR system and Rebate Program, respectively. Likewise, it did not address any claim that laws like H.B. 1473 effect an unconstitutional taking of manufacturers' property. *Id.* at 16

(rejecting judgment on the pleadings for defendants when a manufacturer alleged that the law forced it "to transfer its prescription drugs to private, non-governmental entities—'namely, to contract pharmacies and the covered entities with which they contract'"). Finally, *McClain* did not face a claim that laws like H.B. 1473 are unconstitutionally vague, nor did it consider whether such laws offend the dormant Commerce Clause. In this case, with the claims AbbVie has alleged and the evidence it has submitted, *McClain* has no application.

II. NORTH DAKOTA'S LAW EFFECTS AN UNCONSTITUTIONAL TAKING OF ABBVIE'S PRIVATE PROPERTY.

H.B. 1473 effects an unconstitutional taking of private property. The Takings Clause of the Fifth Amendment, which applies to the states through the Fourteenth amendment, provides: "nor shall private property be taken for public use, without just compensation." H.B. 1473 compels AbbVie to transfer its property to a private party for private gain. Such a transfer is per se unconstitutional.

A. H.B. 1473's Compelled A-to-B Transfer of Property Constitutes a Per Se Physical Taking.

H.B. 1473 is an unconstitutional taking. North Dakota's law compels the "acquisition" of AbbVie's property by third parties, and so effects a "physical appropriation[]" that "constitute[s] the 'clearest sort of taking.'" *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 148 (2021) (quoting *Palazzolo v. Rhode Island*, 533 U.S. 606, 617 (2001)). In practical terms, H.B. 1473 compels AbbVie to complete sales of its property at confiscatory prices that it would not otherwise accept. Ex. 3 (Scheidler Decl.) ¶¶ 31–32.

The law's text confirms as much. It says AbbVie may not "deny, restrict, prohibit, or otherwise interfere with the ***acquisition*** of" its own property "by a contract pharmacy" at the 340B price. *See* N.D. Cent. Code § 43-15.3-08(3)(b)(1) (emphasis added). The ordinary meaning of "acquisition" is the "gaining of possession or control over something." Black's Law Dictionary

(12th ed. 2024). So, AbbVie is prohibited, at risk of severe state penalties, from doing anything that would impede any commercial pharmacy so authorized from taking possession of AbbVie's drugs at a sharp discount. *See* N.D. Cent. Code § 43-15.3-08(3)(b)(1). Stated affirmatively (rather than as a double negative), AbbVie must permit contract pharmacies to acquire its products at confiscatory prices whenever they demand them. *Id.* That is a taking. *Horne v. Dep't of Agric.*, 576 U.S. 350, 361–62 (2015) (explaining that the "actual taking of possession and control" is "a taking as clearly 'as if the [receiving party] held full title and ownership'") (quoting *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 431 (1982)); *Harris* Order at 16 (concluding that a manufacturer stated a claim for an unconstitutional physical taking under an analogous law when it alleged that the state law forced it "to transfer its prescription drugs to private, non-governmental entities—'namely, to contract pharmacies and the covered entities with which they contract'").

The practice on the ground confirms what the text demonstrates. Under AbbVie's current contract-pharmacy policy, AbbVie will accept a covered entity's order for 340B-priced drugs "***provided that***, (i) the covered entity submits limited claims data on 340B utilization for such contract pharmacy location and (ii) the one contract pharmacy is located within 40 miles of the HRSA registered covered entity parent side." Ex. 3 (Scheidler Decl. Ex. E, AbbVie 7/1/2025 Policy) at 1. If a covered entity does not accept those conditions, there is no discounted sale. The effect of H.B. 1473, however, is to eliminate AbbVie's ability to insist upon those conditions. That will result in AbbVie transferring significantly more drugs at confiscatory prices than it would otherwise. *Id.* ¶¶ 31–32.

Because H.B. 1473 confers benefits on wholly private entities, H.B. 1473's taking cannot be saved by the public use doctrine. The oldest rule in takings jurisprudence is that a legislature

may not take property from private party A and give it to private party B. *See Calder v. Bull*, 3 U.S. (3 Dall.) 386, 388 (1798); *Kelo v. City of New London*, 545 U.S. 469, 477 (2005) ("[T]he sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation."). H.B. 1473 does just that. The Supreme Court has made clear that "[a] purely private taking could not withstand the scrutiny of the public use requirement; it would serve no legitimate purpose of government and would thus be void." *Haw. Hous. Auth. v. Midkiff*, 467 U.S. 229, 245 (1984); *see Kelo*, 545 U.S. at 490 (Kennedy, J., concurring) ("[T]ransfers intended to confer benefits on particular, favored private entities, and with only incidental or pretextual public benefits, are forbidden by the Public Use Clause."). H.B. 1473 expands arbitrage opportunities for private entities to reap windfall profits; it is a purely private taking.[3]

H.B. 1473's confiscatory scheme is not voluntary either, unlike the ostensibly voluntary federal/manufacturer relationship at the core of the 340B Program. *See Va. Hosp. & Healthcare Ass'n v. Roberts*, 671 F. Supp. 3d 633, 666 (E.D. Va. 2023) (recognizing that a program's voluntariness under federal law does not render all related state laws voluntary). The voluntary participation doctrine protects against a sovereign asserting a "unilateral claim of entitlement" to "alter property rights" without providing any valuable benefit in exchange. *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 833 n.2 (1987). That does not describe AbbVie's relationship to H.B. 1473. Congress offers manufacturers coverage under federal Medicare and Medicaid on the condition that the manufacturers agree to the requirements of the federal 340B statute as manifested in their pharmaceutical pricing agreement. *See* 42 U.S.C. §§ 256b(a), 1396r-8(a)(1).

[3] Even assuming that the taking is for public use (it is not), AbbVie is still entitled to an injunction until North Dakota provides AbbVie with just compensation for the taking. *Knick v. Township of Scott*, 588 U.S. 180, 206 (2019).

That bargain (contained in the PPA) is the only reason Congress can require manufacturers to transfer their drugs to another private party at steep discounts.

In any purported voluntary exchange, no government may unilaterally demand more but provide no further benefit. For example, in *Valancourt Books*, *LLC v. Garland*, the D.C. Circuit addressed Section 407 of the Copyright Act, which required copyright holders to transfer, under pain of civil penalties, free copies of the "best edition" of their work to the Copyright Office "for use or disposition of the Library of Congress." 82 F.4th 1222, 1227 (D.C. Cir. 2023) (quoting 17 U.S.C. § 407(a)). The court held that the transfers of free materials coerced by Section 407 were uncompensated takings and found no "voluntary exchange" that might save the section. The court observed Section 407's contrast with Section 408. The latter, the court explained, required copy transfer in exchange for benefits—*e.g.*, the right to bring an enforcement action, *prima facie* proof of validity, and so on. But because copyright holders did not need to transfer their works under Section 407 to receive the benefit of their copyright, they "receive[d] no additional benefit for the works they forfeit[ed]" under the law. *Id.* at 1232. That made Section 407 an uncompensated taking.

The same is true here: North Dakota seeks to extract more from manufacturers than the 340B Program demands but provides nothing over and above what Congress (through Medicaid and Medicare coverage) has already offered. *See Horne*, 576 U.S. at 366 (explaining that participating in commerce is "not a special governmental benefit that the Government may hold hostage, to be ransomed by the waiver of constitutional protection"). H.B. 1473 "cannot reasonably be characterized as part of a similar voluntary exchange," *id.*, because North Dakota offers no distinct benefit to AbbVie in exchange for compliance with H.B. 1473—indeed, there was never anything approaching an "offer" in the first instance. North Dakota may well think

Congress was overly generous, but that does not authorize it to rewrite AbbVie's 340B relationship with a different sovereign. Congress offered the carrot of access to Medicaid and Medicare Part B in exchange for the stick of discounted prices. North Dakota offers only another stick: civil and criminal penalties for any manufacturer that does not indulge unlimited for-profit pharmacy usage.

For a prototypical voluntary exchange, look to *Leonard v. Earle*, 279 U.S. 392 (1929). There, under Maryland law, the State owned the oysters in its waters. To obtain a license to fish the State's oysters, fishermen had to give the State 10% of the shells from their catch. *Id.* at 394–95. Because Maryland traded access to State-owned oysters for a portion of the fishermen's catch, there was no taking. *Id.* at 396; *see also Horne*, 576 U.S. at 366–67 (describing *Earle*). Contrast that with *Horne*, which examined the federal government's effort to require raisin growers to remit a portion of their crop each year. *Horne*, 576 U.S. at 355. "Raisins are not like oysters: they are private property," so because the government provided no benefit apart from forbearing enforcement or exclusion from commerce, its actions were a taking. 576 U.S. at 367. North Dakota does not attempt to take a portion of something it already owns when it purports to expand AbbVie's drug distribution requirements.

Other courts have treated "voluntariness" the same way. In *Virginia Hospital & Healthcare Association v. Roberts*, plaintiffs challenged a legal regime that "compel[ed] a private party to devote four hours of professional services time and expend four units of supplies for public use, while in turn furnishing fair compensation for just one hour and one unit of supplies." 671 F. Supp. 3d at 665. The court concluded that the hospitals' relationship with the federal government—Medicare access for an obligation to provide emergency care—was voluntary and thus not a taking. *Id.* at 666–67. But the court concluded that a state law that compelled Medicare participation without offering a further benefit was likely not voluntary before rejecting the takings

claim based on an immunity argument not relevant here. *See id.* at 667. Similarly, even if AbbVie's 340B relationship with the federal government is voluntary, its regulation by North Dakota is not. (After all, civil and criminal penalties do not smack of voluntariness.) North Dakota uses its coercive power to force AbbVie to let it freeride on AbbVie's deal with another sovereign. In doing so, it effects an unconstitutional taking.

B. Although the Regulatory Takings Doctrine Does Not Apply, Even If It Did, AbbVie's Facts Are Sufficient.

H.B. 1473 physically appropriates AbbVie's private property because it compels AbbVie and other drug manufacturers to sell drugs to contract pharmacies at a steep discount. Ordinarily, that sort of direct appropriation would mean the regulatory takings doctrine does not apply. *Horne*, 576 U.S. at 363 ("[W]hen there has been a physical appropriation," courts "do not ask ... whether it deprives the owner of all economically valuable use of the item taken.") (citation modified). In the alternative, however, AbbVie argues that H.B. 1473 effectuates a partial regulatory taking. *See Penn Central Transp. Corp. v. City of New York*, 438 U.S. 104, 124 (1978) (laying out a flexible three-factor test for a regulatory taking: (1) the economic impact of the regulation, (2) the extent to which the regulation has interfered with investment-backed expectations, and (3) the "character of the governmental action").

North Dakota regulates drug acquisition at a discounted price, not delivery, requiring AbbVie and other drug manufacturers to provide contract pharmacies with "access" to the 340B discount when they are not otherwise entitled to it. N.D. Cent. Code § 43-15.3-08(3)(b)(2). This requirement imposes a significant financial burden, compelling AbbVie to mark down covered drugs as much as 99.9% of the average price in the market. 42 U.S.C. §§ 1396r-8(c), 256b(a)(1). In some cases, AbbVie must charge as little as one penny per unit. *See id.* §§ 1396r-8(c), 256b(a)(1); Ex. 3 (Scheidler Decl.) ¶ 31. Manufacturers did not expect state laws like H.B. 1473

to contort section 340B into a multi-billion-dollar for-profit arbitrage scheme. Under federal law, manufacturers may insist on reasonable conditions—including ones that affect contract pharmacies. *Sanofi*, 58 F.4th at 706. H.B. 1473 upsets those expectations in pursuit of a patently unlawful aim: enhancing the commercial performance of retail pharmacy chains and covered entity hospitals. Under the circumstances, H.B. 1473 effects at least a partial regulatory taking. *Harris* Order at 17–18 (concluding that a manufacturer stated a claim for an unconstitutional regulatory taking regarding Arkansas's H.B. 1473 analog). It adds a surprise requirement to federal law and forces AbbVie to transfer its property at artificially low prices—all so that commercial pharmacies and hospitals can resell that property at market price.

III. NORTH DAKOTA'S LAW IS UNCONSTITUTIONALLY VAGUE.

H.B. 1473 is unconstitutionally vague because it "fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits." *Reprod. Health Servs. of Planned Parenthood of St. Louis Region, Inc. v. Nixon*, 428 F.3d 1139, 1143 (8th Cir. 2005) (quoting *Hill v. Colorado*, 530 U.S. 703, 732 (2000)). Such statutes "threaten to hand responsibility for defining crimes to relatively unaccountable police, prosecutors, and judges, eroding the people's ability to oversee the creation of the laws they are expected to abide." *United States v. Davis*, 588 U.S. 445, 451 (2019). That issue is more acute "where a statute imposes criminal penalties." *See Kolender v. Lawson*, 461 U.S. 352, 358 n.8 (1983).

H.B. 1473 forbids manufacturers to "[i]nterfere" with contract pharmacies' "ability to ... dispense" drugs purchased at the 340B discount price to "eligible patient[s]." N.D. Cent. Code § 43-15.3-08(3)(b)(4). This provision is unconstitutionally vague because it tells drug manufacturers almost nothing about the conduct constituting a violation. It cannot prohibit manufacturers' contract pharmacy policies because subsection (3)(b)(2) already does that. *Id.* at § 43-15.3-08(3)(b)(2). It cannot eliminate rebate models; subsection (3)(b)(5) already does that

too. *Id.* § 43-15.3-08(3)(b)(5). And it cannot help covered entities and contract pharmacies conceal claims data, because subsection (3)(b)(3) already does that as well. *Id.* § 43-15.3-08(3)(b)(3). Even if the subsection at issue is a catchall, designed to cover the State's bases, the State must indicate exactly which acts will catch the attention of its enforcers. It has not done so.

What is more, it is not conceptually clear when or how a manufacturer could actually "interfere" with contract pharmacies' "ability to ... dispense" drugs at the 340B price to "eligible patients[s]." N.D. Cent. Code § 43-15.3-08(3)(b)(4). Under the replenishment model, pharmacies dispense drugs from their general inventory at commercial prices to patients ***before*** the black box algorithm guesses whether those sales were 340B-eligible and places an order for replacement drugs at the 340B price. *See* Ex. 2 (Williams Decl.) ¶¶ 24–26f. Pharmacies do not generally dispense at the 340B price, and 340B eligibility is guessed only later at the time of replenishment. *See id.* ¶ 27b-c. The order of operations necessary for § 43-15.3-08(3)(b)(4) to make sense does not happen on the ground.

Another particularly revealing sign of H.B. 1473's vagueness problem is the law's use of the broad term "interfere" without defining it. N.D. Cent. Code §§ 43-15.3-01, 43-15.3-08. When that term appears in other statutes, it often contributes to the conclusion that a statute runs afoul of the vagueness doctrine. *See, e.g.*, *Carolina Youth Action Project; D.S. ex rel. Ford v. Wilson*, 60 F.4th 770, 786 (4th Cir. 2023) (finding it "hard to know where to begin with the vagueness problems" in a statute that "made it a crime to 'wilfully [sic] or unnecessarily' 'interfere with or to disturb in any way or in any place the students or teachers of any school or college in this State'").

Much like its terms, H.B. 1473's structure creates unconstitutional ambiguity. The statute's sections likely have distinct meanings. *Rimini St., Inc. v. Oracle USA, Inc.*, 586 U.S. 334,

346 (2019) ("If one possible interpretation of a statute would cause some redundancy and another interpretation would avoid redundancy, that difference in the two interpretations can supply a clue as to the better interpretation."). Yet they borrow terms from each other—"prohibit," "dispense," "interfere"—and use those terms in slightly different ways. For example, § 43-15.3-08(3)(b)(4) prohibits "[i]nterfere[nce]" with a contract pharmacy's "ability" to "dispense" a drug, whereas § 43-15.3-08(3)(b)(2) states that a manufacturer cannot "[p]rohibit a contract pharmacy from dispensing a drug by denying access to the drug." N.D. Cent. Code § 43-15.3-08(3)(b)(2), (3)(b)(4). It is unclear what the first section accomplishes that the second does not, or vice versa. Instead, the statute expects manufacturers to guess—an unlawful expectation, particularly when incorrect guesses trigger criminal penalties. *Kolender*, 461 U.S. at 358 n.8.

Those penalties apply even when manufacturers intend to comply with the statute. A scienter requirement—requiring, for example, intent—would lessen the concern that H.B. 1473 is impermissibly vague. *Nixon*, 428 F.3d at 1143. But it does not contain one. The statute compounds that problem when it refers to "eligible patient[s]," since that term is defined by covered entities and their contract pharmacies. N.D. Cent. Code § 43-15.3-08(3)(b)(4). Their definitions will often be a secret, since covered entities and contract pharmacies select their own definitions and need not disclose them. *See* Ex. 3 (Scheidler Decl.) ¶ 11.

This combination of ambiguity and discretion renders H.B. 1473 "so standardless that it invites arbitrary enforcement." *Johnson v. United States*, 576 U.S. 591, 595 (2015). State officials decide whether manufacturers have improperly "interfered" with the acquisition of drugs by covered entities and contract pharmacies—and they ask those entities how to define operative terms in the statute. In this way, H.B. 1473's vague provisions create a serious due process concern. Its vague and overlapping terms deny drug manufacturers notice of the law that will be

applied to their conduct. It invites arbitrary enforcement on the say-so of covered entities and contract pharmacies. *See id*. This includes criminal penalties, so AbbVie cannot administer its program without risking "a class B misdemeanor." N.D. Cent. Code § 43-15.3-08(3)(b). Laws structured to produce such results deny regulated entities their due process rights.

IV. NORTH DAKOTA'S LAW OFFENDS THE DORMANT COMMERCE CLAUSE.

A state statute may violate the dormant Commerce Clause doctrine if it "directly regulate[s] out-of-state transactions by those with *no* connection to the State," or if it "clearly discriminates against interstate commerce in favor of in-state commerce." *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 376 n.1 (2023) (citing *Edgar v. MITE Corp.*, 457 U.S. 624, 641–43 (1982)); *Grand River Enters. Six Nations, Ltd. v. Beebe*, 574 F.3d 929, 942 (8th Cir. 2009). The same is true if a state statute "impos[es] a burden on interstate commerce that is 'clearly excessive in relation to the putative local benefits.'" *Entergy Ark., LLC v. Webb*, 122 F.4th 705, 711 (8th Cir. 2024) (quoting *LSP Transmission Holdings, LLC v. Sieben*, 954 F.3d 1018, 1026 (8th Cir. 2020)), *cert. denied*, 145 S. Ct. 2849 (2025); *see also Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). H.B. 1473 violates the dormant Commerce Clause doctrine three times over.

First, H.B. 1473 discriminates against out-of-state drug manufacturers, and in favor of in-state pharmacies and hospitals, by forcing the manufacturers to sell additional quantities of discounted drugs. Ex. 3 (Scheidler Decl.) ¶¶ 31–32. The statute does so by dramatically expanding the pool of individuals who can access the discounted drugs that covered entities can buy at discounted prices, including individuals who do not qualify as patients of the covered entity. *See id.* ¶¶ 17e, 19. When a manufacturer sells to a covered entity in North Dakota, H.B. 1473 ensures that the manufacturer cannot guard against diversion as it can in other states and under federal law. *See Sanofi*, 58 F.4th at 703–06. As a result, covered entities and their contract pharmacies in North Dakota receive more drugs at the deeply discounted 340B price. Indeed, H.B.

1473 purports to extend contract pharmacies the same entitlement to 340B pricing as covered entities. N.D. Cent. Code § 43-15.3-08(3)(b)(2). This sort of raw protectionism, in which a state "'build[s] up ... domestic commerce' through 'burdens upon the industry and business of other States,'" violates core dormant Commerce Clause principles. *Nat'l Pork*, 598 U.S. at 369 (quoting *Guy v. Baltimore*, 100 U.S. 434, 443 (1880)).

Second, H.B. 1473 burdens interstate commerce significantly more than it benefits North Dakota. The statute forces out-of-state manufacturers to provide discounted drugs to North Dakota covered entities and contract pharmacies. This "simple economic protectionism" is an illegitimate legislative interest. *Nat'l Pork*, 598 U.S. at 372. In pursuit of that illegitimate interest, the statute imposes several significant burdens. It forces manufacturers like AbbVie to sell drugs they would not otherwise offer to sell, given the magnitude of the 340B discount. And the statute adds to a growing patchwork of state 340B laws, each with distinct requirements and each purporting to regulate transactions with a national character. *See* Ex. 3 (Scheidler Decl.) ¶ 22. Manufacturers like AbbVie must map these conflicting state-level requirements onto nationwide contracts with wholesalers and distributors, incurring costs and risking liability in the process.

The scheme's purported benefits do not outweigh the substantial burdens it places on interstate commerce, in no small part because the benefits will not flow to North Dakotans. Section 340B does not require covered entities to charge their patients less for discounted drugs. *See generally* N.D. Cent. Code § 43-15.3-08. Nor does it require covered entities to pass along savings some other way, whether at contract pharmacies or otherwise. *See generally id.* As a result, covered entities are increasingly unlikely to pass along 340B savings to their patients. Ex. 1-G (GAO Rep., GAO-18-480) at 35, 43–44; *see also* Ex. 2 (Williams Decl.) ¶ 44 (estimating that "less than 5 percent (perhaps less than 2 or 3 percent)" of 340B transactions "involve any sort of direct

patient discount"). Seeking to maximize their arbitrage opportunities, covered entities require or allow unsuspecting insured patients to pay commercial price for 340B drugs. Ex. 3 (Scheidler Decl.) ¶ 16. They do so even when, in some cases, those drugs cost the covered entity as little as 0.01% of the commercial price. *See* 42 U.S.C. §§ 1396r-8(c), 256b(a)(1). They then share these profits with national pharmacy chains like Walgreens and CVS.

Third, H.B. 1473 regulates out-of-state transactions with little or no connection to North Dakota. The statute forbids pharmaceutical manufacturers to "[d]irectly or indirectly deny, restrict, prohibit, or otherwise interfere with the acquisition of a drug by a contract pharmacy on behalf of a covered entity." N.D. Cent. Code § 43-15.3-08(3)(b)(1). Nor may manufacturers deny contract pharmacies "access" to drugs—that is, drugs "purchased under reduced pricing under section 340B." *Id.* § 43-15.3-08(3)(a)(3), (3)(b)(2). In addition to these restrictions, H.B. 1473 prevents manufacturers from "[i]nterfer[ing] with the ability of a covered entity or contract pharmacy to dispense a drug to an eligible patient of the covered entity." *Id.* § 43-15.3-08(3)(b)(4). These prohibitions sweep over manufacturers' "agent[s]," too, as well as "affiliate[s]," "virtual manufacturer[s]," and "third-party logistics provider[s]." *Id.* § 43-15.3-08(3)(b). They apply without reference to the location of a covered entity, a contract pharmacy, or their patients. Under the statute, a contract pharmacy is one "that has a contract with a covered entity to receive and dispense drugs … on its behalf." *Id.* § 43-15.3-08(3)(a)(1). A covered entity is one "participating or authorized to participate in" the 340B Program. *Id.* § 43-15.3-08(3)(a)(2). As a result, H.B. 1473 permits the Board of Pharmacy and Attorney General to punish AbbVie for its interactions with a Texas covered entity that purchases drugs and provides them to a pharmacy in Arkansas—or its interactions with a Minnesota covered entity that contracts with a North Dakota pharmacy.

In either instance, the actual sale takes place entirely outside of North Dakota, yet AbbVie is potentially subject to H.B. 1473's penalties.

H.B. 1473 imposes a substantial burden on drug manufacturers and the national prescription-drug industry. In effect, it compels manufacturers to sell discounted drugs on North Dakota's terms—even when those transactions occur in other states. And it does so primarily on behalf of private pharmacies and hospitals. As explained, nothing requires that patients receive discounts on their prescriptions because of 340B. H.B. 1473 concurs in that result, as it does not require covered entities and contract pharmacies to pass the 340B discount along to patients. Instead, the discount accumulates in covered entities and contract pharmacies, which buy 340B drugs at steep discounts and then sell as many of them as possible at full price. Ex. 2 (Scheidler Decl.) ¶ 16. The dormant Commerce Clause doctrine does not permit a state to pursue such aims. *Webb*, 122 F.4th at 711.

CONCLUSION

The Court should grant summary judgment in favor of AbbVie. It should permanently enjoin the State from enforcing H.B. 1473 against AbbVie.

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Respectfully submitted,

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